

### **REMARKS/ARGUMENTS**

The Office Action of March 9, 2006 has been carefully reviewed and this paper is the Applicants' response thereto. Claims 1-23 are pending in the application. Claims 1-14 and 16-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,639,234 ("Badura") and claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,540,681 ("Strul"). In response, the Applicants respectfully traverse the rejections in view of the above amendments and the following remarks.

#### **Rejection under 35 U.S.C. §103 – Badura**

Claims 1-14 and 16-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Badura. The Applicants respectfully traverse the rejection.

Badura is directed to a method of checking the beam guidance of a heavy ion beam therapy system where the beam guidance is checked for various purposes. (Col 6, lines 49-53). Such purposes include, for example, generating the treatment beam (col. 6, lines 54-55), checking the beam guidance at the irradiation site (col. 8, lines 62-63), checking the absolute beam location and the location stability (col. 9, lines 22-23), monitoring and control of the absolute beam profile (col. 10, lines 38-40), monitoring the particle count (col. 11, lines 31-32), checking of movable components (col. 11, lines 60-62), etc. In particular, Badura provides for a second channel to terminate a treatment beam in the event that the treatment beam is not terminated by a first termination request:

Starting from the accelerator, it must be ensured that termination of extraction is effected when there is a termination request. Should the treatment beam not be terminated by the termination request, that fact is ascertained by the supervisory control system and safety system by means of an intensity measurement, and termination of the beam is requested again by way of a separately provided redundant channel. That second request acts on a corresponding deflection dipole of the high-energy beam guidance channel. In order to check the functionality of that redundant termination of extraction, the alarm line provided for the first termination of extraction is artificially interrupted. In that case, the afore-described second termination of extraction ought to be triggered automatically, which can be tested analogously to the above-described test for the normal termination of extraction. If termination of extraction does not occur within 10 ms, appropriate intervention is necessary. In order to check consistency, that test can be carried out prior to each block of irradiation procedures. (Col. 3, lines 1-18) (emphasis added).

Accordingly, Badura teaches the use of a redundant channel to issue another termination request

if the treatment beam is not terminated by the first termination request. Moreover, whether termination is was achived the first time is determined by “means of an intensity measurement.” Finally, Badura suggests that termination of extraction may not occur even after the second termination request since “appropriate intervention is necessary” if termination does not occur within 10ms.

The pending claims, on the other hand, are directed to a time-based automatic termination of the treatment therapy, regardless of whether a first termination request ever issued. Claim 1 provides as follows (emphasis added):

1. A method for providing redundant back-up to ensure a treatment therapy provided by a medical device system is turned off comprising the steps of:
  - (a) receiving an ON command signal to activate delivery of the treatment therapy to a patient;
  - (b) initiating a cycle ON timer to operate for a predetermined cycle ON time;
  - (c) delivering the treatment therapy to the patient;
  - (d) determining whether the cycle ON timer has expired prior to receiving an OFF command;
  - (e) if the OFF command is received, turning off the treatment therapy; and
  - (f) if the cycle ON timer has expired prior to receiving the OFF command, turning off the treatment therapy regardless of whether the OFF command signal is received.

Similarly, claim 11 provides “wherein the second component is also responsive to the cycle ON timer for causing termination of delivery of the treatment therapy in the event that the second component does not receive an OFF command from the first component for a period longer than a predetermined cycle ON time and during which time the treatment therapy is being delivered.” Unlike the claimed inventions, Badura implements a second termination upon failure of the first termination request. Moreover, Badura determines failure of the first termination request by means of an intensity measurement. The claimed invention, on the other hand, is directed to a different technique where treatment therapy is turned off either upon receiving an OFF command or after a predetermined time period, whichever is earlier. Under the claimed inventions, treatment therapy is terminated after a predetermined time even if an OFF command never issues. In contrast, this would not be possible under Badura. Rather, Badura bases issuance of a second termination only upon failure of a first termination request. Accordingly, there simply is no teaching, disclosure or suggestion in Badura for terminating a treatment therapy as claimed in

the present application.

The Office Action ostensibly recognizes this deficiency in Badura and states that it would have been “obvious to use a timer for timing the interval between the first termination request and the second termination request.” (p. 3). The Applicants respectfully disagree. First, because Badura monitors the particle count in the treatment beam, there would be no need for a timer in the Badura system. Badura provides that a higher particle count could trigger an alarm and the interlock unit triggers switching off the beam.<sup>1</sup> (Col. 11, lines 50-52). Accordingly, there is no need for a timer in the Badura system nor is any suggestion for using a timer. Second, timing the interval between the first and second termination requests would not result in the claimed inventions. The pending claims are directed to timing the total amount of time that the treatment therapy is being delivered and turning off the treatment therapy if that time exceeds a predetermined value, regardless of whether an OFF command is received. Measuring the time interval between the first and second termination requests simply fails to satisfy this claimed feature of the pending claims.

The Office Action has not suggested that any reference can correct the above deficiency, nor have the Applicants found any such teaching or disclosure in Badura. Accordingly, the Office Action fails to make a *prima facie* case of obviousness with respect to claim 1. See MPEP 706.02(j) (“To establish a *prima facie* case of obviousness, three basic criteria must be met. ... [Third], the prior art reference[s] ... must teach or suggest all the claim limitations.”). Accordingly, claims 1 and 11 are patentable over Badura.

Claims 2-10, 12-14 and 16-23 depend from claim 1 or 11 and are patentable over the reference of record for at least the reasons discussed above with respect to claims 1 and 11 and for the additional features recited therein.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

#### **Rejections of 35 U.S.C. §103 – Strul**

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Strul. Claim 15 depends from claim 11 and provides:

15. The medical device system of claim 11, wherein the second component is an implanted device.

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<sup>1</sup> Significantly, this particle count is for purposes of monitoring the variation in the particle count because “the intensity of the treatment beam delivered by the accelerator should vary only within certain tolerance limits.” (Col. 11, lines 31-37).

The Applicants respectfully traverse the rejection. First, the Office Action utterly fails to make a *prima facie* case of obviousness with respect to claim 15. See MPEP 706.02(j) (“To establish a *prima facie* case of obviousness, three basic criteria must be met. ... [Third], the prior art reference[s] ... must teach or suggest all the claim limitations.”). There is simply no discussion of how Strul discloses, teaches, or even suggests the limitations of claim 15 (which also include the limitations claim 11). Notably, the Office Action has not rejected claim 11 in view of Strul.

Strul is directed to a method for radiofrequency ablation where the RF energy is controlled based on temperature and power. Similar to Badura discussed above, because Strul monitors temperature and power, there is no need for a timer in the Strul system nor is there any suggestion for using a timer. Moreover, the Applicants fail to understand how Strul can render obvious claim 15 (but somehow not claim 11) and believe the rejection is in error.

Even if Strul and Badura were combined, the Applicants respectfully submit that claim 15 is patentably distinct for at least the reasons stated above with respect to the traversal of the rejection of claim 11 in view of Badura.

Accordingly, withdrawal of this ground of rejection is respectfully requested.


### CONCLUSION

All rejections having been addressed, the Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Respectfully submitted,

Dated: June 9, 2006

By:

  
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